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RVD2009-03

Re-evaluation Decision

Dichloran

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Overview

Re-evaluation Decision

After a re-evaluation of the fungicide dichloran, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing dichloran for sale and use in Canada.

An evaluation of available scientific information found that products containing dichloran do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of dichloran uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested as a result of this re-evaluation.

The regulatory approach for the re-evaluation of dichloran was first presented in Proposed Re-evaluation Decision PRVD2008-21, *Dichloran*, a consultation document.¹ This Re-evaluation Decision² describes the PMRA's regulatory process for the re-evaluation of dichloran as well as summarizes the Agency's decision and the reasons for it. Appendix I summarizes the comment received during the consultation process and provides the PMRA's response to this comment. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-21. To comply with this decision, registrants of products containing dichloran will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers the potential risks and value of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Dichloran, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents.

For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of dichloran. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated dichloran and published its conclusions in a 2006 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-21, *Dichloran*.

What Is Dichloran?

Dichloran is a fungicide used to control brown rot (*Monilinia fructicola*) and Rhizopus rot (*Rhizopus* sp.) on fruits (i.e. preharvest and postharvest peaches and postharvest sweet cherries), as well as white mold (*Sclerotium cepivorum*), sclerotinia rot and sclerotinia drop (*Sclerotinia sclerotiorum*) on some vegetables (i.e. lettuce, onions, garlic, beans [dry, snap and pole] and greenhouse tomatoes), and grey mold, stem canker and blight caused by *Botrytis* sp. on certain outdoor and greenhouse ornamentals (chrysanthemum, rose, hydrangea and geranium). Dichloran is also currently registered for use as a space/surface spray in rose and hydrangea storage areas. However, this use is no longer supported by the registrant. Dichloran end-use products are formulated as a wettable powder and are applied using hand-held or groundboom equipment, or used in a dipping solution for postharvest fruits.

Health Considerations

Can Approved Uses of Dichloran Affect Human Health?

Dichloran is unlikely to affect your health when used according to the revised label directions.

People could be exposed to dichloran by consuming food and water, working as a mixer/loader/appligator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that dichloran was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Dichloran is currently registered in Canada for use on peaches, lettuce, onions, garlic, beans (dry, snap and pole), greenhouse tomatoes and sweet cherries and could be used in other countries on crops that are imported into Canada.

In Canada, there are maximum residue limits (MRLs) established for dichloran³ i.e.:

- 20 ppm on snap beans;
- 15 ppm on peaches, nectarines and sweet cherries;
- 10 ppm on apricots, blackberries, celery, grapes, lettuce, raspberries and strawberries;
- 5 ppm on carrots, onions, plums, rhubarb, sweet potatoes and tomatoes; and
- 0.5 ppm on cucumbers and garlic.

Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to set permanent MRLs.

³ Food and Drug Regulations, Division 15: Adulteration of food, and Tables.

Environmental Considerations

What Happens When Dichloran Is Introduced Into the Environment?

Dichloran is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target organisms (i.e. birds, mammals, insects, aquatic organisms and terrestrial plants) could be exposed to dichloran in the environment.

Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern.

The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of dichloran was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required. Furthermore, the PMRA is requiring aquatic buffer zones for dichloran to protect aquatic organisms from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of dichloran, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixers/loaders/applicators
- A restricted-entry interval to protect workers re-entering treated sites

Environment

- Additional advisory label statements to reduce potential surface water and groundwater contamination
- Buffer zones to protect non-target, sensitive aquatic habitats
- Changes to maximum application rates

Appendix II lists all required label amendments.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide the following data or an acceptable scientific rationale to the PMRA for confirmation of aquatic buffer zones and calculation of terrestrial buffer zones.

- DACO 9.4.2—Non-target Marine Invertebrates; Acute (Crustacean)
- DACO 9.4.5—Non-target Marine Invertebrates; Chronic (Mollusk or Crustacean)
- DACO 9.5.2.4—Acute Studies; Marine/Estuarine Fish
- DACO 9.8.4—Non-target Plants – Terrestrial Vascular Plants

These studies must be conducted with a Canadian end-use product or a product with an equivalent formulation and guarantee. They must also be conducted according to the appropriate USEPA Office of Prevention, Pesticides and Toxic Substances or Organisation for Economic Co-operation and Development guidelines.

Other Information

Any person may file a notice of objection⁴ regarding this decision on dichloran within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

⁴ As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Comment on Data Requirements

An aerobic aquatic metabolism half-life of 1828 days was used by the PMRA to calculate its aquatic buffer zones for dichloran. This value was taken from the 2006 USEPA RED. The registrant has submitted a new aerobic metabolism study to the USEPA and the PMRA. The USEPA found this study acceptable and concluded that the half-life of dichloran in water-sediment systems was 3.4–3.5 days. The additional data required in the Proposed Re-evaluation Document PRVD2008-21, *Dichloran*, were based on the assumption that dichloran is extremely persistent in the environment. In view of the new available data, the additional toxicity data requested by the PMRA are not warranted.

Response

Limited toxicity data was available for dichloran. Additional data are required in order to complete terrestrial buffer zone calculations and to confirm that the proposed interim aquatic buffer zones adequately protect sensitive marine habitats. The aerobic metabolism study submitted to the PMRA does not provide additional toxicity data; therefore, the data requirements for dichloran remain unchanged.

However, the interim aquatic buffer zones for dichloran have been recalculated by the PMRA based on the new half-life of this chemical in water-sediment systems. Appendix II lists the revised interim aquatic buffer zones for dichloran.

Appendix II Label Amendments for Products Containing Dichloran

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

- I) The structural use on rose and hydrangea storage areas is not supported by the registrant; references to this use must be removed from the relevant labels.
- II) The maximum application rates indicated in the last two columns of the table below must be included on the end-use product labels.

Uses	Currently on Labels		Supported Application Rates	
	Maximum Rate Per Application	Maximum Rate Per Year	Maximum Rate Per Application	Maximum Rate Per Year
Peaches	5.06 g a.i./L	None specified	1.3 kg a.i./ha*	3.9 kg a.i./ha
Onions/garlic	33 kg a.i./ha	None specified	4.5 kg a.i./ha	4.5 kg a.i./ha
Pole beans	3.8 kg a.i./ha	None specified	3.8 kg a.i./ha	4.5 kg a.i./ha
Dry and snap beans	2.44 kg a.i./ha	None specified	2.44 kg a.i./ha	4.5 kg a.i./ha
Lettuce	2.8 kg a.i./ha	4.6 kg a.i./ha	2.8 kg a.i./ha	4.5 kg a.i./ha
Greenhouse tomatoes	1.3 g a.i./L	None specified	1.3 g a.i./L	3 applications per year
Rose and hydrangea (field or stored)	1.3 g a.i./L	None specified	1.3 g a.i./L	None specified
Rose, geranium and chrysanthemum (stock cuttings or greenhouse plants)	0.7 g a.i./L	None specified	0.7 g a.i./L	None specified
Stored food (postharvest) Peach/ sweet cherry	1.3 g a.i./L	None specified	1.3 g a.i./L	1.3 g a.i./L

* The label currently indicates 1.3 g a.i./L. This must be modified to 1.3 kg a.i./ha.

- III) The **PRECAUTIONS** section of all end-use product labels must include the following label statements.

Wear a long-sleeved shirt, long pants, shoes and socks during mixing, loading, application, clean-up and repair activities. In addition, wear chemical-resistant gloves during mixing/loading, clean-up and repair activities, and a NIOSH-approved respirator during mixing and loading activities.

Should the registrant choose to package the end-use product in water soluble bags, the use of a respirator during mixing, loading would no longer be a requirement.

Do not apply this product in a way that will cause this product to contact workers or other persons, either directly or through drift. Only handlers (mixers, loaders and applicators) wearing personal protective equipment may be in the area being treated during application.

Do not enter or allow worker entry into treated areas for 12 hours following application.

- IV) The **ENVIRONMENTAL HAZARDS** section of all end-use product labels must include the following label statements.

For outdoor applications: Do not apply this product directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats.

For indoor applications: Do not allow effluent containing this product to enter lakes streams, ponds or other waters. For guidance contact the provincial Regulatory Agency.

- V) The **ENVIRONMENTAL HAZARDS** section of the end-use product Registration Number 8772 label must include the following label statements.

TOXIC to aquatic organisms. Observe buffer zones specified under **DIRECTIONS FOR USE**.

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted, fine textured, or low in organic matter such as clay).

Avoid application of this product when heavy rain is forecast.

Do not contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

- VI) The **DIRECTIONS FOR USE** section of the end-use product Registration Number 8772 label must include the following statements.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification.

Airblast application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. DO NOT apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

DO NOT apply by air.

DO NOT apply this product through any type of chemigation system.

Buffer zones: The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:			
		Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Field sprayer*	All crops	2	1	1	1
Airblast (early growth stage)	Peaches	20	2	5	2
	All others	25	3	10	3
Airblast (late growth stage)	Peaches	10	2	4	2
	All others	15	2	4	2

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

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